

IAP9 Rec'd PCT/PTO 24 MAR 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bryan, et al.

Serial No.

Filed:

For: OPTIMIZED EXPRESSION OF HPV 45 L1 IN YEAST

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

**EXPRESS MAIL CERTIFICATE**  
DATE OF DEPOSIT March 24, 2006  
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DATE 3-24-06

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

~~MERCK & CO., INC.~~

By \_\_\_\_\_ Date \_\_\_\_\_

10/573330  
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## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

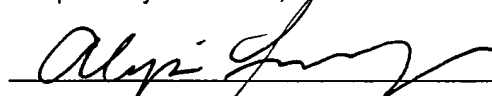
RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Alysia A. Finnegan

Attorney \_\_\_\_\_ For Applicant(s)

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Date: March 24, 2006



Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>COMPLETE IF KNOWN</b>		
			Application Number	<b>10/573330</b>	
			Filing Date	<b>IAP9 Rec'd PCT/PTO 24 MAR 2006</b>	
			First Named Inventor	Bryan, et al.	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	21500

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bosch, et al., "Prevalence of Human Papillomavirus in Cervical Cancer: a Worldwide Perspective", J. Nat. Cancer Inst., Vol. 87, No. 11, June 7, 1995, pp. 796-802.
		Breitbart, et al., "Immunization with Viruslike Particles from Cottontail Rabbit Papillomavirus (CRPV) Can Protect Against Experimental CRPV Infection", J. of Virol., Vol. 69, No. 6, June 1995, pp. 3959-3963.
		Delius, et al., "Primer-Directed Sequencing of Human Papillomavirus Types", Curr. Topics in Microbiology and Immunology, Vol. 186, 1994, pp. 13-31.
		GenBank Accession No. Q9Y4Y5
		Kortula, et al., "Evaluation of Foreign Gene Codon Optimization in Yeast: Expression of a Mouse IG Kappa Chain", Bio/Technology, Vol. 9, December 1991, pp. 1386-1389.
		Liu, et al., "Polynucleotide viral vaccines: codon optimization and ubiquitin conjugation enhances prophylactic and therapeutic efficacy", Vaccine, Vol. 20, 2002, pp. 862-869.
		McMurray, et al., "Biology of human papillomaviruses", International Journal of Experimental Pathology, Vol. 82, 2001, pp. 15-33.
		Neeper, et al., "Expression of the major capsid protein of human papillomavirus type 11 in Saccharomyces cerevisiae", Gene, Vol. 180, 1996, pp. 1-6.
		Schiffman, et al., "Epidemiologic Evidence Showing That Human Papillomavirus Infection Causes Most Cervical Intraepithelial Neoplasia", Journal of National Cancer Institute, Vol. 85, No. 12, June 16, 1993, pp. 958-964.
		Schiller, et al., "Developing HPV virus-like particle vaccines to prevent cervical cancer: a progress report", Journal of Clinical Virology, Vol. 19, 2000, pp. 67-74.
		Schiller, et al., "Papillomavirus-Like Particles: Basic and Applied Studies", Papillomavirus Reviews: Current Research on Papillomaviruses, ed. Leeds, UK: Leeds Medical Information, 1996, pp. 101-112.
		Sharp, et al., "Synonymous Codon Usage in Saccharomyces cerevisiae", Yeast, Vol. 7, 1991, pp. 657-678.
		Suzich, et al., "Systemic immunization with papillomavirus L1 protein completely prevents the development of viral mucosal papillomavirus", PNAS, Vol. 92, December 1995, pp. 11553-11557.
		Tobery, et al., "Effect of vaccine delivery system on the induction of HPV 16 L1-specific humoral and cell-mediated immune responses in immunized rhesus macaques", Vaccine, Vol. 21, 2003, pp. 1539-1547.
		Zhou, et al., "Papillomavirus Capsid Protein Expression Level Depends on the Match between Codon Usage and tRNA Availability", J. of Virol., Vol. 73, No. 6, June 1999, pp. 4972-4982.

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.